

APPENDIX G: DEVELOPMENT COSTS AND EXPECTED RETURNS

In assessing the possible impacts of the rule on industry's decisions to develop new products, it is important to have a sense of the magnitude of regulatory costs in comparison to the costs of product development and to expected returns. This section reviews some evidence from the survey on development costs and expected returns.

A. Product Development Costs

The survey data on yearly research expenditures provide some insights into development costs although the survey results do not explicitly contain data on the expected total costs of developing products. Of the firms responding to the survey, 52 gave estimates of their research budgets. Of these 52, 50 indicated both the fraction of research devoted to biotechnology and the fraction of biotechnology research falling under TSCA. For these 50 firms, then, it was possible to estimate total R&D spending devoted to TSCA-related biotechnology by multiplying the R&D budget first by the biotechnology-related percentage and then by the TSCA-related percentage. For example, a firm reporting that it spends \$10,000,000 per year on R&D, with 70 percent of the total related to biotechnology and 50% of biotechnology research devoted to TSCA areas, is assumed to spend \$10,000,000 times 70 percent times 50 percent, or \$3,500,000 annually on TSCA biotechnology R&D.

Of the 50 firms for which an estimate of R&D spending on TSCA products could be made, 41 provided a breakdown of products in R&D by type of manipulation. These 41 firms reported a total of 214 products, both natural and modified, under development. Seventeen of the 41, with a total of 97 products in R&D, reported having only naturally-occurring products under development. Another 17, with a total of 67 products in R&D, reported having no naturally-occurring products. The remaining 7 firms indicated that they

are developing products of both types; they reported a total of 50 products in R&D.

Knowing the annual per-product R&D expenditures does not answer the question of the total budget for developing each product from start to finish because the average number of years to develop a product is unknown. For illustrative purposes, this analysis assumes that a typical product development process lasts five years.* Table G-1 presents the estimated typical (median) and average development costs (based on a 5-year development cycle) for products of all firms; average costs are also shown separately for firms with all naturally-occurring products and all engineered products to show clearly the higher costs associated with developing engineered microorganisms.**

These figures must be interpreted cautiously for a number of reasons. First, multiplying through the chain of percentages could introduce a significant amount of error. For example, inaccuracies in estimates of total budgets are magnified by inaccuracies in the respondent's estimates of the percentage devoted to R&D. Second, for cases in which more than one product is under development by a single firm, it was not possible to discern the range in expenditures across the firm's products. That is, the majority of the yearly expenditures could be absorbed by only one of the products, with the others requiring minimal R&D spending. In addition, research expenditure rates change over the course of development; a firm whose projects are in

* One industry analyst points out that few firms have products on the market yet, and that development times appear to be on the order of two to ten years (Science 1987).

** Notice the wide difference between the median and the mean. This difference indicates that the distributions are highly skewed, with a few very large values pulling the average up, and many smaller projects.

Table G-1. Typical and Average Product Development Expenditure

Product Type	Median Product Development Cost	Average Product Development Cost
All Product Types (41 firms, 214 products)	\$ 167,000	\$1,500,000
Products of Firms with Naturally-Occurring Products Only (17 firms, 97 products)	\$ 50,000	\$ 844,000
Products of Firms with Recombinant and Altered Products Only (17 firms, 67 products)	\$1,250,000	\$2,790,000

Note: This analysis assumes that the product development process lasts five years. Seven firms, with a total 50 products in R&D, were working with both natural and engineered microorganisms.

Source: ICF 1988.

early exploratory stages might seem to be spending small amounts on research per product compared to a firm whose products are at the most intense phase of development.

B. Expected Returns

A measure of the returns a firm expects from a prospective product is even more important than a measure of development costs in predicting whether or not a given increase in regulatory costs will affect the firm's decision to proceed with development. Despite relatively high regulatory costs as compared to development costs, a firm might proceed if it expects extremely high returns from the product. Similarly, even a costly project could be derailed by a small regulatory cost if the project were expected to produce only modest returns.

Although expected returns are more difficult to estimate than development costs, the survey data (ICF 1988) provide some insight into expected returns. Respondents were asked for an estimate of the minimum projected returns they require before they would proceed with a project (termed here their profit hurdle). Thirty firms both responded to this question and provided information on their products, allowing estimates of the average and median profit hurdles associated with products of different types. Profit hurdles are presented in Table G-2. As with product development costs, average values are higher than median values, and values for naturally-occurring products are lower.

The hurdle rates appear strongly related to the costs of product development. That is, firms that expect to reap more in returns once their product are commercialized are spending more on R&D per product each year. This observation is in line with our expectations that more valuable products are generally more difficult and costly to develop than products with low payoffs.

Table G-2. Typical and Average Minimum Profit Hurdles

Product Type	Median Profit Hurdle	Average Profit Hurdle
All Product Types (30 firms, 150 products)	\$ 750,000	\$5,035,000
Products of Firms with Naturally-Occurring Products Only (12 firms, 59 products)	\$ 175,000	\$4,683,000
Products of Firms with Recombinant and Altered Products Only (13 firms, 49 products)	\$ 750,000	\$5,912,000

Note: Five firms with a total of 42 products were working with both natural and engineered microorganisms.

Source: ICF 1988.